U.S. House of Representatives
Committee on Energy and Commerce
Testimony before the Subcommittee on Health
"Increasing Generic Drug Utilization: Saving Money for Patients"

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Mr. Chairman, members of the Committee: Thank you for inviting me to testify before you today.

Allow me to briefly introduce myself, and then tell you how my experience relates to what I am going to discuss today. I am a practicing physician and a former senior advisor to the Commissioner of the Food and Drug Administration and the Administrator of the Centers for Medicare and Medicaid Services.

At FDA and then at CMS, I worked on many policies that were promulgated during my time at those two agencies that were aimed at increasing the availability of safe and effective generic drugs, and providing a framework for people to make wider use of them.

But it is as a physician that I have developed my deepest appreciation for the value that generic drugs offer.

Practicing in a mostly Medicaid clinic, I often had to approach my patients' prescription requirements not on what they needed, but what they could afford. They could only spend a fixed and usually small amount of money each month – out of pocket – on medicines.

Generic drugs make it possible for me to provide my patients with the lifesaving benefits of safe and effective medicines, while staying within their tight budgets.

This is not a unique recognition, but one made also by policymaker across Washington, and especially on this committee. So the question becomes: what steps can we take to encourage more widespread use of safe and effective, FDA approved generic drugs where these options make sense for patients both a therapeutically

and economically, without trampling the incentives for brand drug makers to continue to come up with newer and yes better molecules by dismantling legitimate patent protections.

The good news is that each year, patients are making wider use of generic drugs, recognizing the value that they bring. Drug insurance companies, which are exposing consumers to more of the cost of their incrementally more expensive medical choices, are also driving this trend. Through aggressively tiered formularies or co-pays on more expensive branded drugs, consumers who can afford to contribute to the incremental cost of expensive taste when it come to medicines, are being asked to pay a portion of that that decision.

This is giving consumers reason to make wider use of low cost generic options, and even over the counter drugs, where these substitutions for branded drugs make therapeutic sense.

One recent study by Aetna of almost 14,000 beneficiaries found a 5.5 percent decrease in pharmacy costs and a 7 percent increase in overall generic utilization when consumers were exposed to more of the cost of their incremental drug decision.

There is also some evidence from MEDSTAT and elsewhere that Medicare beneficiaries who have been using the new Medicare drug cards are more likely than other seniors to use generic drugs, I think precisely because the information they have available through the drug card keeps them informed and educated on how much they can save with generic drugs.

I believe these trends to expose consumers who can afford to pay to some of the cost of their decisions will accelerate under the new Medicare Prescription Drug Plan, as the plans themselves become more aggressive, and adept at managing a drug benefit and steering patients to lower cost options where they exist and where they offer similar therapeutic benefits.

But there are some things that we should all be mindful of.

First, the decision that plans make about which medicines to have high co-pay on, or to have prior authorization on, is often not linked

directly to the cost of the medicine, or its value to the patient relative to the generic alternative, but simply on whether the plan got a good deal from the drug company.

So a far better way to expose consumers to the incremental cost of more expensive drug decisions is through Health Savings Accounts, or through co-insurance.

Of course, patients have to want to participate in their own health care decision-making, or be able to, and not everyone will. So we need to maintain a safety net for those who cannot.

Second, if we are going to truly take advantage of some of the opportunities to offer more patient-specific therapies in the future, using tools like genomics and proteomics, then it simply follows that the patient will need to be a more active participant in weighing competing medical options that will all have certain benefits and tradeoffs, including economic tradeoffs.

So what can this Committee do to help us prepare for this future of consumer led healthcare? I think one of the big impediments to more active participation by consumers is the lack of information – at the point of care – about the economic impact of peoples' decisions. Far too often, I prescribe a medicine to a patient only to get a phone call a few hours later. They are at the pharmacy and found out there is a $50 co-pay on the medicine I prescribed. Can I find something else for them that does not have a co-pay.

It is simply impossible for me to keep track of all of the different formularies from all of the different plans that all of my different patients are on. Having this information accessible right in my office, and having it available outside of my office for my patients, would give my patients and I the information tools we need to factor economics into our choices.

I am confident, that armed with that information, we would opt for lower cost generics – where they make therapeutic sense – more often than we do today.

That leads me to my last point: How can we make this information more widely available? Here I encourage you to look at some recent steps that Aetna has taken. They have developed a sophisticated web site that allows patients to mix and match similar drugs to see how they can lower their overall drug bill by changing their drug mix.

This is one area where I also believe that CMS is taking the lead and setting a good example for the private market, through efforts like their drug compare web site and pushing for incentives and standards to promote more widespread adoption of e-prescribing.

I believe government can play an appropriate role, following the lead set by CMS, to help patients have more information available to them so that they can weight for themselves the value generic drugs offer at the time that they need to make decisions about which drug they want to use.

Finally, I'd like to close on two cautionary thoughts for the Committee to consider:

First, especially in an age when decisions to take the drugs that are in development today are going to involve more personal preferences and involve criteria that allow doctors to more closely match medicines to patients, I do not believe policies that force patients into generic drugs will succeed in maximizing overall public health benefit.

Strategies like "Fail First" -- especially when inappropriately applied to areas of medicine where compliance is such a big factor to success, like mental health -- has already been shown to cost more in the end. If plans are going to steer patients to generic drugs through restrictions on access to branded alternatives, they need to provide easy ways to opt around these restrictions for patients for whom the branded drug makes the most sense.

Second and lastly, I believe we all need to recognize that no two molecules are the same. While two very similar drugs, in the same drug "class" might provide largely equal benefits for the majority of patients, there are always patients for whom one seemingly similar drug will have very different affects than its close cousin.

As doctors we see this anecdotally every day and the literature supports our experience. In fact, we cannot have it both ways – recognizing for example that Vioxx might have certain risks that another similar drug does not, yet not recognizing that seemingly similar molecules also have different benefits.

To end on my point about the direction of the technology and of drug development, we are heading toward more targeted treatments, better information about those treatments, and drugs more finely matched to individual patient needs.

We simply cannot adopt policies that force square pegs into round holes, forcing patients on to medicines when better options exist, simply because of cost. We cannot take that decision away from the doctor and the patient. Doing so bucks the tide of innovation and best practice.

What we can, and I think should do, is arm consumers who want to be more active participants in their health choices, and who have the economic means and wherewithal to do so, with information that can help them weigh economics as one more factor in their treatment decisions. Too often in my own medical practice I have been left in my office, scratching my head along with my patient, wondering what the drug bill will be when my patient arrives at their pharmacy.

With all of the valuable information tools we have at our fingertips, there is no reason we need to be left asking these questions. Armed with the right information at the right time, I am confident more of my patients will make wider use of safe and effective generic drugs when these therapeutic options make equal sense.

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